

Remarks

Claims 1- 28 were pending in the subject application. Due to a Restriction Requirement, claims 17-28 have been withdrawn. By this Amendment, the applicant has amended claim 1 and cancelled claim 2. Support for the amendment to the claim can be found throughout the specification. No new matter has been added by these amendments. Accordingly, claims 1 and 3-16 are before the Examiner for consideration.

The amendment to the claim has been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendment should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Initially, the Office Action indicates that the Declaration and Power of Attorney form submitted to the Patent Office is defective due to changes made to the applicant's address without initialing or dating the change. Further, the Declaration and Power of Attorney is defective due to the incorrect date of the priority claim. The applicant is in the process of obtaining a newly executed Declaration and Power of Attorney form.

Claim 1 has been objected to due to informalities. By this amendment, the applicant has amended claim 1 to recite "the step of" as suggested by the Examiner. The applicant appreciates the Examiner's careful review of the claims and her helpful suggestions.

Claims 1, 3-5, 7, 8, 12 and 15 have been rejected under 35 U.S.C. §102(b) as being anticipated by Sutton *et al.* (WO 97/36578). The applicant respectfully traverses this ground for rejection because the cited reference does not disclose each and every element of the claimed invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim.

*Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir.

1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

By this Amendment, the applicant has amended claim 1 to incorporate the subject matter of previous claim 2, which recites that the stabilizing carbohydrate is trehalose. Please note that this anticipation rejection was not previously applied to claim 2. The cited reference does not disclose the use of trehalose as a stabilizing carbohydrate. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102 based on Sutton *et al.*

Claims 1, 2 and 13-15 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bot *et al.* (WO 00/00215). The applicant respectfully traverse this ground of rejection because the cited reference does not disclose each and every element of the claimed invention.

Bot *et al.* disclose that trehalose can be used as an excipient to provide structure (see page 24); however, this publication does not teach the method of the present claim 1 whereby a mixture of viral particle and trehalose are spray dried using an outlet temperature of no more than 60° C. The Office Action cites Example XIV of the Bot *et al.* publication as being relevant for the novelty of the claims. However, this example relates to the preparation of microparticles by spray drying a virus with hydroxyethyl starch using an outlet temperature of 61° C.

Because the cited reference does not disclose each and every element of the claimed invention, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §102 based on Bot *et al.*

Claim 2 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sutton *et al.* (WO 97/36578) as applied to claim 1 above and further in view of Roser *et al.* (U.S. Patent No. 6,190,701). Please note that claim 2 has been cancelled herein; however, to the extent that this rejection might be applied to the claims now presented for examination, the applicant respectfully traverses because the cited references, either taken alone or in combination, do not

disclose or suggest the applicant's unique and advantageous method for producing a micro-particle dry powder.

Roser *et al.* has been cited because it teaches that trehalose can be used to stabilize molecules. However, if the skilled person were to combine the teachings of these two publications, and therefore choose trehalose as the stabilizing carbohydrate, they would also employ the process conditions taught in relation to making microparticles comprising trehalose.

In Example 1, Roser *et al.* teach that when producing particles by spray drying using trehalose, an outlet temperature of 7- 75° C should be used, which would affect virus viability. The present invention requires an outlet temperature of no more than 60° C, and results in improvements in viability after drying.

The mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.*

In the present case there would be no reason for the skilled artisan to combine the teachings of the cited references to arrive at the current invention. Therefore the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

Claims 3-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bot *et al.* (WO 00/00215) as applied to claim 1 above. The applicant respectfully traverses this ground for rejection because the cited reference does not disclose or suggest the current invention.

As noted above, the Bot *et al.* reference describes a process utilizing different conditions. There is no apparent motivation to modify the Bot *et al.* process to successfully arrive at the invention as now claimed.

An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection,

as was specifically recognized by the CCPA in *In re Sponnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

Claims 9-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sutton *et al.* (WO 97/36578) or Bot *et al.* (WO 00/00215) as applied to claim 1 above. The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the subject invention.

The shortcomings of these references with respect to the current invention have been discussed above. The present invention requires an outlet temperature of no more than 60° C, and results in improvements in viability after drying. If Bot and Sutton are either taken alone, or combined, the process conditions will still be too high.

Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

Claim 16 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sutton *et al.* (WO 97/36578) or Bot *et al.* (WO 00/00215) as applied to claim 1 above and further in view of LiCalsi *et al.* 1999 (*Vaccine* 17:1796-1803). The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the subject invention.

The shortcomings of the primary reference with respect to the current invention have been discussed above. The LiCalsi *et al.* reference does not cure or even address these defects.

Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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